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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/776,724	02/06/2001	Steven M. Ruben	PZ011	2764

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EXAMINER
LY, CHEYNE D

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 12/03/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/776,724	Applicant(s) RUBEN ET AL.	
	Examiner Cheyne D Ly	Art Unit 1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,13,16-20,22 and 24-53* is/are pending in the application.

4a) Of the above claim(s) *1,13,16-20 and 22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24 - 53* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,13,16-20,22 and 24-53* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Applicant's election with traversal of Group II, SEQ ID NO: 142, claims 24-53, in Paper No.11, filed September 19, 2002, is acknowledged.

2. The traversal is on the ground(s) that it would not be unduly burdensome to perform a search on claims 1-23 together. This is not found persuasive because nucleic acids, polypeptides and antibodies are directed to different chemical types regarding the critical limitations therein. It is acknowledged that various processing steps may cause a peptide to be directed as to its synthesis by a polynucleotide or an antibody to be directed as to its synthesis by a peptide, however, the completely separate chemical and entity types of the inventions of the polynucleotide, poplypeptide and antibody support the undue search burden if they were examined together. Further, the distinct methods of use corresponding to each chemical type support the undue search burden if they were examined together. While taking advantage of the distinct properties of each chemical type, these usages have distinct goals as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

3. The requirement is still deemed proper and is therefore made FINAL.

4. Claims 24 - 53 are examined on the merits.

LACK OF UTILITY UNDER 35 U.S.C. § 101:

5. The pending claims have been reviewed in light of the the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first

paragraph, "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

6. The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

7. Claims 24-53 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

8. The claimed subject matter is not supported by a specific and substantial utility because the disclosed uses are generally applicable to broad classes of this subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably

confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter.

9. Specific to the activation of the EGR1 pathway, Applicant discloses in the specification (Page 121, Lines 10-20) that "when tested against sensory neurons cell lines, supernatants removed from cell containing this gene activated the EGR1 pathway. Thus, it is likely that this gene activates sensory neuronal cells, or more generally, neural cells, in addition to, other cells or cell types, through the EGR1 signal transduction pathway. ...And this gene is expressed primarily in osteoclastoma." Applicant fails to provide *specific* and *substantial* disclosure that this gene activates the EGR1 pathway in cells that are not from cell lines. Therefore, such disclosure does not provide adequate support for the intended utilities of the claimed invention. As disclosed by the applicant, the polypeptide is useful as reagents or immunological probes for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of diseases and conditions" (Page 121, Lines 21-23). The disclosed intended use is specific to cells in tissues or biological samples not cell lines. It is acknowledged that cell lines are important models for studying biological mechanisms, however, the fact they are cell lines cause them to be different from cells that have not been manipulated to be immortalize as cell lines. Cells in a culture undergo a genetic change that makes them effectively immortal. "Such cells will proliferate indefinitely and can be propagated as a cell line.... It is important to recognize, however, that the cells in cell lines nearly always differ in important ways from their normal progenitors in the tissues from which they were derived. (Molecular Biology of the Cell, Page 4, Lines 2-17)." The lack of disclosure that the polypeptide of SEQ ID NO:142 activates the EGR1 signal transduction pathway in cells that are not from cell lines as specified by the

intended uses causes the claimed subject matter to fail to meet the *specific* and *substantial* utility requirement. Therefore, the disclosure fails to support the intended utility of SEQ ID NO: 142 as reagents or immunological probes for differential identification of the tissue(s) or cell type(s) present in a biological sample and for diagnosis of diseases and conditions.

LACK OF ENABLEMENT UNDER 35 U.S.C. § 112, FIRST PARAGRAPH:

Claims 24-53 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

NEW MATTER UNDER 35 U.S.C. § 112, FIRST PARAGRAPH

10. Claims 24-28, 34-38, and 44-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The amended subject matter in these claims is considered to be new matter because they are not disclosed in the original specification. This is a NEW MATTER rejection.

11. It is acknowledged that Applicant cited Pages 121-122 and Table 1, Page 140, row 7 as support for the claimed invention. In considering the above support, this is the rationale for following NEW MATTER rejections; SEQ ID NO:142 has the following features: First AA of Sig. Pep is 1, Last AA of Sig. Pep is 53, First AA of Secreted Portion is 54, and Last AA of ORF is 54. Therefore, there is written basis for a polypeptide of amino acid sequence 1-53 or 54 and thereof.

12. Specific to Claim 24, the introduction of an isolated protein comprising amino acids 1 to 54 from SEQ ID NO:142 is regarded to be new matter. Claim 25-28, 34-38, and 44-48 are also reject for being dependent from Claim 24.

INDEFINITENESS UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

13. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

14. Claims 24-53 are rejected under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

15. The data in Table 1 Row 7 suggests that after the removal of the signal peptide the functional secreted peptide of the SEQ ID NO:142 is one amino acid, number 54. However, the claim invention is directed to either an amino acid of SEQ ID NO:142 length 1-54 in Claim 24 or 2-54 in Claim 25. The conflict between the disclosure in Table 1 Row 7 and the Claims 24 and 25 causes the claims to be vague and indefinite.

16. Claims 29, 30, 39, 49 and 50 contain abbreviations, such as ATCC, that cause the claims to be vague and indefinite unless accompanied by the full name in parentheses. Claims 31-33, 40-43, and 50-53 are also rejected for being dependent from Claims 29, 30, 39, 49 and 50.

17. Claims 34-43 all contain, either directly or indirectly via dependence, limitations directed to certain percentages of identical sequence, such as 90 % or 95 %. These sequence limitations are confusingly reasonably interpretable in two very different ways. One interpretation is that the percentage of identical sequence is determined by noting what percentage of the claimed polypeptide itself contains amino acid residues which are the same as in the polypeptide as

defined by the SEQ ID NO: in the claims. In this interpretation a subsegment, including a small subseqment, of a polypeptide defined by a SEQ ID NO: in the claims may be an embodiment of the instant claims. A second and different interpretation is that the claimed polypeptides are evaluated via the percentage of amino acid residues of the polypeptide defined by the SEQ ID NO: that is cited in the claims. Thus the 100% standard for percentage evaluation may be evaluated from the percentage of claimed polypeptide amino acid residues vs. the percentage of SEQ ID NO: defined amino acid residues which is contained within the claimed polypeptide. The instant claims as worded do not distinguish between these two interpretations, albeit that the latter interpretation may be what is meant by the applicants. Clarification of the metes and bounds of the percentage evaluation as required in the instant claims via clearer claim wording is requested.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 34-37 and 39-42 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sigma Catalog, 1990.

3. The above publication Sigma Catalog discloses a polypeptide FL (Phenylalanine and Leucine) Product Number P 03876 (Page 802), which is 100% identical to either the polypeptide of SEQ ID NO: 142 or a polypeptide encoded by the HOSKD95 cDNA at positions 43-44. Clearly, the invention disclosed in the Sigma Catalog anticipates the limitation of a first

polypeptide at least 90% or 95% identical to a second consisting of amino acid residues 1-54 of SEQ ID NO:142 or consisting of the complete polypeptide encoded by the HOSDK95 cDNA. Further, the invention of the Sigma Catalog anticipates the limitations of a heterologous polypeptide or a composition of the said polypeptide and an acceptable carrier.

18. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

21. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
12/2/02

ARDIN H. MARSCHEL
PRIMARY EXAMINER